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Exhibit 481B

CMS/
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and CHIP Services

JWie I, 2012

Dear Pharmacy Owner / Manager:

As you are aware, changes in the availability of drug pricing benchmarks necessitate that many State Medicaid programs evaluate alternative pricing methods for use in reimbursing pharmacies for drugs that they dispense. Because of these changes, we have the unique opportunity to work together to recognize the contributions pharmacists make to the health of Medicaid recipients through the realignment of drug ingredient reimbursement for estimating pharmacy's acquisition costs, and the provision of reasonable Medicaid dispensing fees that consider professional services performed by pharmacists.

The Centers for Medicare and Medicaid Services (CMS) is working with State Medicaid prognuns, with input from national phannacy associations and many other stakeholders, regarding the design and development of a National Average Drug Acquisition Cost (NADAC) reference file. We expect that the NADAC reference file will represent a new pricing benchmark based on the national average costs that pharmacies pay to acquire Medicaid covered outpatient drugs. This pricing benchumuk will be based on drug acquisition costs collected directly from pharmacies through a nationwide survey process. This survey will be conducted on a monthly basis to ensure that the NADAC reference file remains current and up-to-date.

CMS envisions that the NADAC reference file will provide State Medicaid agencies with an additional Jllicing reference which they can use to evaluate their current drug reimbursement methodologies. I fa Medicaid prognun chooses to utilize the NADAC reference file for drug ingredient reimbursement, we expect that States will simultaneously evaluate their Medicaid dispensing fee.

One of the primary goals ofUtis proo,ram is to create and maintain an up-to-date NADAC reference list for Medicaid covered outpatient drugs reflecting the average price paid for drugs by entities(e.g., independent phannacies and chain phannacies in the United States). The drug acquisition cost survey process has been designed to minimize the administrative burdens on pharmacies that participate and to streamline the process of obtaining drug cost data from pharmacies.

CMS has contracted with Myers and Stauffer LC, a national certified public accounting firm that provides professional accounting, consulting, data management and analysis services to government-sponsored healthcare progrruns. Myers ruld Stauffer has extensive experience working with State Medicaid pharmacy progrruns and collecting acquisition costs directly from pharmacies. Under tlris CMS contract, Myers aJid Stauffer has developed a methodology for collecting drug acquisition costs aJid calculating the NADAC reference file prices for covered outpatient drugs.

A meeting with stakeholders was held on August 4, 2011 at the CMS offices in Baltimore, during which the proposed methodology for the NADAC was presented. Since that meeting, further stakeholder input has been received and considered in the final design and develoJlJlent

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OMS Control 11038-1041

of the drug acquisition cost survey and NADAC reference file initiative. Additional information and routine updates will be available from the http://www.Medicaid.gov website.

Your pharmacy has been randomly selected to participate in this month's survey. We are requesting that you provide a copy of the selected purchase invoices for drugs purchased by your phannacy. The attached survey instructions prepared by Myers and Stauffer outline the survey process for submitting one (1) month's worth of drug invoices by fax, mail, or electronic submission. Since 2,000 to 2,500 pharmacies nationwide are randomly selected to participate in the survey each month, the probability that your pharmacy will be selected again during the year is 5% or less. Based on the contractor's experience, it is estimated to take less than 30 minutes ofnon-phannacist time to assemble and submit the requested information.

It is important to note that all drug purchase price information submitted for this project will remain under the control ofCMS, will only be used for the purposes described above, and will remain secure to the extent provided by law, consistent with Exemption 4 of the Freedom ofInformation Act (FOIA). Accordingly, neither CMS nor Myers and Stauffer will release invoice information and pharmacy identification that is submitted voluntarily and is identified by you as proprietary, except as is required by law.

By parlicipaling inlIte survey, yuu will have llte uppmturrily lu ensure lltalllte markel cumliliuns facing your pharmacy are represented in the calculation and evaluation of the NADAC. One of the goals of the NADAC program is to account for the prices that phannacies pay to acquire drugs.

To accomplish this goal, information from your pharmacy is necessary. Your participation in this endeavor is strongly encouraged and greatly appreciated.

This Retail Price Survey represents an opportunity for Medicaid phannacies to participate in an initiative to determine a reference price representing the acquisition cost of drugs. Please note that current Federal regulations require State Medicaid programs to consider the professional services performed when setting their dispensing fee rates.

Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions regarding this survey.

Sincerely,

Barbara Coulter Edwards

Barbara Coulter Edwards
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Center for Medicaid and CHIP Services

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

June 1, 2012

Your pharmacy has been randomly selected for a sampling of invoices. We are requesting your pharmacy provide the following information within 14 days:

1) Copies of all wholesaler, distributor, or manufacturer invoices, reflecting all brand, generic and OTC drug purchases transacted with all your wholesale supplier(s) and/or drug manufacturer(s) between

May 1, 2012 through May 31, 2012

2) Enclosed Cover Sheet (on gold-colored paper), if identifying submitted information as proprietary and confidential

These records are to be limited to drug ingredient costs only. All costs that are not drug ingredient costs, such as those for shipping, storage, warehousing, or other administrative costs or other internal mark-ups, will not be considered when calculating the NADAC. For purposes of this survey, drug ingredient costs should represent the invoice price paid by your pharmacy to an unrelated third party supplier of outpatient drugs, such as your wholesaler or drug manufacturer. Drug ingredient costs charged to your pharmacy by related parties that also include administrative costs or other mark-ups will not be included in the NADAC calculations. Please do not submit any patient-identifiable information.

Information should be submitted in printed or electronic format and should include the following information:

1) National Drug Code (NDC)
2) Purchase price of drug (drug ingredient cost only-see instructions above)
3) Quantity purchased
4) Purchase date for each product
5) "Item number"-to-NDC crosswalk, if item numbers or other proprietary nomenclature is used on your invoices.

As a time-saving alternative to you or your pharmacy staff submitting invoice records, you may contact your drug supplier(s) to request and authorize them to forward an electronic or hard copy of your purchasing history (as described above) for the requested period directly to Myers and Stauffer LC. Please do not include any invoices that include Public Health Services 340B drug pricing.

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OMB Control #0938-1041

Information should be mailed, faxed, or sent electronically to the following address within 14 days

Myers and Stauffer LC
Attention: CMS Pharmacy Survey
9265 Counselors Row, Suite 200
Indianapolis, IN 46240-6419

OR

317-816-4134 FAX

OR

survey@mslcrps.com (Please indicate "CMS Pharmacy Survey - confidential and proprietary" in the subject line.)

PLEASE USE THE ENCLOSED COVER SHEET (ON GOLD-COLORED PAPER) WHEN SUBMITTING YOUR PHARMACY'S INFORMATION TO IDENTIFY THIS INFORMATION AS PROPRIETARY. FAILURE TO DO SO MAY MEAN IT WILL NOT BE CONSIDERED PROPRIETARY.

Please be aware that information submitted will not be returned, therefore, please submit copies or electronic files of these records. Your participation in this endeavor is strongly encouraged and greatly appreciated. Please contact the Help Desk operated by Myers and Stauffer LC at (855) 457-5264 should you have any questions.

PRA Disclosure Statement

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1041. The time required to complete this information collection is estimated to average 30 minutes per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Office, Mail Stop C4-26-05, Baltimore, Maryland 21244-1850.

OMB Control #0938-1041

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Medicaid and CHIP Services

COVER SHEET

National Average Drug Acquisition Cost (NADAC) Survey Request for Information

TO: Myers and Stauffer LC
ATTENTION: CMS Pharmacy Survey

9265 Cmmselors Row, Suite 200
Indianapolis, IN 46240-6419

OR

317-816-4134 FAX

OR

survey@mslcrps.com
(Please indicate "CMS Pharmacy Survey confidential and proprietary" in the subject line.)

The data contained in this submission is proprietary and confidential financial information that has been submitted voluntarily.

OMB Control #0938-1041

NADAC Calculation

- Data should be from surveyed pharmacies
- Data should be for valid and active NDCs
- Data should be for the calendar month under review
- NDCs should be on CMS covered outpatient drug product file or approved for inclusion by CMS (newly available covered outpatient drugs)
- NDCs should not have a DESI code of 5 or 6
- Only one NDC cost observation for each pharmacy is included – the most recent observation within survey period

NADAC Calculation (cont.)

Outliers

- Cost observations greater than +/- two standard deviations from the mean are removed
- A manual drug-by-drug group review is also completed and additional outliers are removed (e.g., obvious outliers, erroneous data, etc.)
- Manual review process supported through use of statistical tools

NADAC Calculation (cont.)

Calculations

- Cost data are compiled and summarized for each individual drug group
- S/I drugs that experienced price changes after the invoice date will be adjusted based on the relative change in its published drug prices
- Unit cost for each reported NDC within the individual drug group is arrayed from highest to lowest
- The number of pharmacies that purchased the NDC at the same unit cost is determined
- The NADAC average acquisition cost per unit is calculated

NADAC Calculation (cont.)

The table below illustrates how the average acquisition cost is calculated for an individual drug group.

SIMVASTATIN 20 MG TABLET

NDC	Drug Name	Generic Rating	Drug Package	Package Size (a)	Package Cost (b)	Unit Cost (c=b / a)	Cost Observations (d)	Factor (e = c x d)
65862005290	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	8.96	0.09956	1	0.09956
68180047901	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	2.45	0.08167	9	0.73503
65862005290	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	6.12	0.06800	1	0.06800
16714068301	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	2.00	0.06667	1	0.06667
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	31.66	0.06332	3	0.18996
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	5.69	0.06322	1	0.06322
16714068301	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	1.77	0.05900	1	0.05900
16714068302	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	4.06	0.04511	3	0.13533
68180047902	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.82	0.04244	5	0.21220
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.77	0.04189	1	0.04189
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.52	0.03911	6	0.23466
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	38.56	0.03856	1	0.03856
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	37.54	0.03754	1	0.03754
68180047902	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.37	0.03744	1	0.03744
68382006716	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.34	0.03711	1	0.03711
16714068302	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.27	0.03633	1	0.03633
16729000515	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.27	0.03633	1	0.03633
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	35.76	0.03576	2	0.07152
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	35.39	0.03539	30	1.06170
68382006705	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	17.36	0.03472	4	0.13888
00093715456	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	30	1.04	0.03467	7	0.24269
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	3.11	0.03456	1	0.03456
16714068303	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	34.33	0.03433	4	0.13732
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	16.75	0.03350	1	0.03350
55111019905	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	500	16.42	0.03284	2	0.06568
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	32.73	0.03273	1	0.03273
68382006710	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	31.48	0.03148	5	0.15740
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	31.44	0.03144	3	0.09432
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.93	0.03093	2	0.06186
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.77	0.03077	1	0.03077
68382006710	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	30.36	0.03036	2	0.06072
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	28.05	0.02805	3	0.08415
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	27.32	0.02732	8	0.21856
00093715498	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	2.45	0.02722	41	1.11602
68180047903	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	26.81	0.02681	3	0.08043
16729000515	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	2.25	0.02500	9	0.22500
55111019990	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	90	1.86	0.02067	3	0.06201
16729000517	SIMVASTATIN 20 MG TABLET	AB	BOTTLE	1000	19.60	0.01960	3	0.05880

Manufacturers in Sample	7	All A-rated Generic Manufacturers	17	173	6.19745	
NDCs in Sample	16	All A-rated Generic NDCs	47			

Average Acquisition Cost (e / d): 0.03582

NADAC Updates

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- NADACs will be reviewed for updates on both a weekly and monthly schedule
  - Weekly due to changes in published prices (i.e., WAC)
  - Weekly due to inquiries into NADAC Help Desk
  - Monthly based on new survey data

NADAC Updates (cont.)

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- Smoothing
  - Monthly average acquisition costs will be compared to existing NADAC
  - NADACs will be updated weekly for changes in published prices
  - Small percentage changes month-to-month likely do not reflect price changes but changes in the composition of the respondents
  - If the percentage change month-to-month is small, no change will be made to published NADAC. If percentage change is large, the NADAC will be revised

NADAC Updates (cont.)

Single Source or Innovator Multiple Source Drugs (S or I drugs)

- Percentage Change Threshold
  - For the top 500 brand drugs, there were 1,433 published price changes during the year
  - Only 8 published price changes were for 2% or less
  - Update/Revision Threshold: Change in average cost is greater than 2%

NADAC Updates (cont.)

Non-innovator Multiple Source Drugs (N drugs)

- NADACs will be reviewed for updates on both a weekly and monthly schedule
  - Weekly due to inquiries into NADAC Help Desk
  - Monthly based on new survey data
- Monthly based on new survey data
  - If an existing NADAC cannot be updated due to a lack of data from a subsequent monthly survey, the current NADAC drug will stay on the reference file until the sooner of 1) a month for which a new NADAC can be calculated, or 2) twelve (12) months from the initial NADAC date

NADAC Help Desk

- Staffed by certified pharmacy technicians, trained analysts and pharmacists
- Help Desk support is limited to:
  - Survey Support – questions related to the survey process, options for responding to survey, what information to submit, or other survey related questions
  - Drug price changes – notification of recent drug price increases not reflected in posted NADAC file
- Help Desk will not address pharmacy inquiries into specific State or claim reimbursement related questions or concerns

NADAC Help Desk (cont.)

- Drug Price Change Inquiries
  - Each inquiry will be researched and addressed in a timely fashion
  - Research will include comparison to costs collected through survey, confirmation of drug or material shortages, and confirmation of price changes with other community pharmacies
- Validated drug price changes will be reflected in weekly updates

NADAC Help Desk (cont.)

- Due to the expected volume, the results of individual pharmacy inquiries will not be communicated directly back to the pharmacy, but instead, if a change is confirmed it will be included in a weekly update
- Pharmacies may call back into the help desk to receive an update on the status of their inquiry if they are unclear of the resolution

NADAC File

- The NADAC file will be posted to the Medicaid.gov website on a weekly basis
- Each new file will be a full replacement of the previous file
- Meeting with compendia to discuss sample file layout and update processes

Questions / Comments

- For additional information or to submit questions or comments
  - Email: RPS@cms.hhs.gov
  - Website: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html

- For those unable to attend this webinar, a taping of the presentation and related slides will be available on the website above for one week following the webinar.

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

Submitted via email to RPS@cms.hhs.gov

June 21, 2012

Barbara Edwards
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Subject: NCPA Comments on "Part II: Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC)"

Dear Barbara:

On behalf of the National Community Pharmacists Association (NCPA), I am writing regarding the recently released CMS document, Draft Methodology for Calculating the National Average Drug Acquisition Cost (NADAC). NCPA appreciates the opportunity to review this guidance and provide our comments and concerns before states may have the option to utilize results of these surveys to reimburse community pharmacies. NCPA represents the owners and operators of approximately 23,000 privately-held small business independent community pharmacies across the United States. Our members provide about 41 percent of all outpatient prescriptions in the United States. Moreover, more than 90% of NCPA members' business is derived from prescription revenues, and Medicaid represents an average 15% of all prescriptions filled. This percentage is higher for pharmacies in urban and rural areas.

NCPA continues to be committed to working with CMS to develop an effective and adequate Medicaid pharmacy reimbursement model for Medicaid. Moreover, the Affordable Care Act (ACA) would increase Medicaid enrollment by millions, making it even more critical that there is a sustainable Medicaid pharmacy reimbursement model.

NCPA does not believe that CMS has the authority to publish NADAC data or acquisition cost data. If Congress wanted CMS to publish these data it would have explicitly said so. CMS disingenuously relies on another part of the statute specifying CMS collection of "consumer purchase prices" to justify its development of a NADAC survey. This refers to "retail survey price" (RSP) – not NADAC. Consumer purchase prices have nothing to do with acquisition costs paid by pharmacies. Moreover, in spite of its misinterpretation of the law, CMS uses the most noncommittal language possible in asking states to simply "evaluate" their dispensing fees if they use NADAC. CMS must require states choosing to utilize NADAC to also implement an accurate dispensing fee through a proper state-specific survey process.

We submit the following comments and observations regarding the draft NADAC methodology. We hope that you will take these items into consideration when calculating the NADAC.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Background and General Comments

- NCPA remains extremely concerned with the process that has been implemented regarding NADAC. CMS is not authorized by Congress to collect NADAC data; thus, this represents an unfunded mandate on small businesses. NCPA appreciates that CMS mentions in the draft the option for pharmacies to contact their wholesalers to produce and send the requested information on their behalf. However, NCPA understands it may be the case that wholesalers are unwilling to do so, with the sole burden falling on small business independent pharmacies.

- In general, there is a severe lack of clarity regarding data sources that will be used to assist with NADAC calculation. For example, the draft methodology is vague regarding where the "Pharmacy Entity Type" will be obtained. Also, CMS needs to clearly state which "multiple national drug pricing compendia" will be used in order to verify that NDCs meet certain NADAC criteria. NCPA urges CMS to provide more clarity in this regard.

- NCPA has concerns with FUL values that might be set below NADAC. This suggests that one or both of the metrics are not accurately measuring what is intended to be measured. Therefore, for multiple source drugs, CMS should never set an FUL value below the NADAC value. CMS has the authority to set FULs at higher than 175% of the weighted average AMP. If CMS does not want to set FULs for all pharmacies at greater than 175% of the weighted average AMP, it should do so for small independent community pharmacies. OIG reports show that independents purchase generic drugs at a higher cost than warehousing chains, justifying a higher price for smaller businesses.

- CMS needs to make clear to pharmacies in the survey instrument that providing the data to CMS is voluntary, which is not clearly stated. CMS gives pharmacies no incentive to provide these data when it fails to commit that use of NADAC by states will be accompanied by a mandatory increase in dispensing fees.

- At this time it is unclear if CMS retains the legal authority to post NADAC data to their website or forward wholesale ingredient cost data to states. CMS cannot rely on the RSP language in Section 1927 to collect and publish these data because that does not give CMS the authority to collect acquisition cost data.

- CMS should explicitly specify that states may not utilize NADAC data for purposes of reimbursement unless a state also updates cost of dispensing fees paid to pharmacies to an appropriate level.

Level of Reporting

- The draft methodology is not entirely clear on how NADAC values will be calculated. In most cases, NADAC will be calculated at the drug grouping/drug category/ pharmacy type level and then reported at the NDC-11 level. But, in other cases additional parameters are included in the definition of drug grouping. As an example, CMS states "package size will be included for additional delineation when there is demonstrated variance of acquisition costs among package sizes for drugs in which the most cost effective package size cannot be purchased and easily repackaged for dispensing." CMS needs to statistically estimate what justifies a large degree of variance of acquisition costs.

Data Collection – Monthly Survey Process

- CMS states they will use a national pharmacy compendia file to identify retail versus chain pharmacy, but there appears to be no standard definition for how CMS will classify chain and independent pharmacy.

- CMS should justify what constitutes a minimum number of responses based on pharmacy type and geographic region. CMS must be clearer regarding what type of geographic distribution will be required to result in a statistically significant response. The number of observations for each entry should be included in the file.

- CMS claims that the time necessary to respond to survey requests should take no longer than thirty minutes of non-pharmacist staff time. However, NCPA has been contacted by multiple small pharmacy owners who have received requests to participate and have reported it requires substantially more time than thirty minutes. The time required to respond appears to be based on the technology available to the pharmacy as well as their wholesaler's willingness to assist. We agree that 340B prices should be excluded.

- CMS states "discounts or rebates that are not listed on the invoice will not be collected." CMS needs to estimate the level of bias created as a result of including rebates in some cases but not in others.

- A pharmacy should NOT have to clarify on a cover sheet their intent for submitted information to remain confidential. ALL information submitted should remain confidential and NCPA requests this change be made.

NADAC Calculation

- CMS states that if a pharmacy submits more than one cost observation for the same NDC, the lowest cost will be used to calculate the NADAC. This would appear to unfairly skew the NADAC downwards to the lowest possible cost of that item. The purpose of NADAC should be to estimate the true cost of a product. By arbitrarily dropping the higher cost values, CMS defeats the purpose of calculating a true acquisition cost. The cost of the drug may have increased within the month to the pharmacy, and that higher-cost product may still be sitting on the pharmacy's shelves.

- CMS states they will use only one cost observation per NDC per pharmacy. This suggests that they are not using all the information available to them to calculate a true NADAC value.

- CMS states that "The NADAC for each classification defined by drug grouping, drug category, and pharmacy type will be calculated as the average of the per-pricing unit cost, in accordance with NCPDP standards, weighted by the submitted acquisition costs." The term "weighted" is unclear. CMS should provide an example as to how they plan to calculate "weighted" averages without utilization data.

- CMS states that for each NADAC "cost observations greater than +/- two standard deviations from the mean are to be removed as outliers." CMS does not mention if this methodology applies in the case of highly skewed data. In some cases standard deviation is not the appropriate metric to use to remove outliers. CMS should report the mean, median, standard deviation, and a measure of skewedness for each NADAC before and after controlling the data for outliers.

- CMS does not justify what constitutes a minimum number of responses for a drug product to have a statistically valid NADAC. CMS simply states: "A minimum number of reported drug costs for each drug grouping/drug category/pharmacy type will be required to calculate a NADAC. This minimum number will be determined in accordance with the initial pharmacy drug acquisition cost surveys received." If CMS receives two reported drug costs, will this meet the minimum number? CMS needs to explicitly state what constitutes a valid sample. What confidence interval and confidence level will be required?

- The calculation of the NADAC as the "per-pricing unit costs…weighted by the submitted acquisition costs" is unclear. Is CMS simple averaging the observations? How will it assure that there is adequate representation in the observations used from independent pharmacies?

- For an innovator multiple source drugs written with a restrictive prescription, will CMS publish a NADAC value for that drug, as well as include that value in the NADAC for a noninnovator multiple source drug when a non restrictive prescription is written?

NADAC Updates

- CMS will conduct monthly surveys, but on a weekly basis, CMS plans to adjust values based on 1. "Research initiated by pharmacy inquiries," and 2. "Published prices." CMS needs to develop and publish a methodology that explains what justifies a weekly change.

- If CMS cannot publish a NADAC, is it because CMS didn't collect enough observations to create a valid NADAC? The cost to pharmacies could have increased, but CMS may not have collected sufficient observations to be able to publish the NADAC value. This is unfair to pharmacies.

- CMS needs to quantify how many pharmacy inquiries justify a price change. Furthermore, CMS needs to clarify what published prices they are utilizing to update weekly values. Is the intent of pharmacy inquiries and published prices to create a new metric to benchmark acquisition costs? It is not clear why CMS would collect monthly survey data if pharmacy inquiries and published prices are used to drive weekly cost values that can then override NADAC values.

- CMS states that "the assignment of a NADAC to a particular NDC does not constitute the status of the NDC as a covered outpatient drug." Why would a NADAC be assigned to a non-covered outpatient drug?

- We agree that updates for drugs should happen weekly. This is especially important for brand name drugs where price increases happen regularly.

- How does CMS intend to develop a NADAC or acquisition cost value for new drugs where invoice data have not yet been collected?

- The states should be required to use the NADAC file as updated weekly; not be able to underpay pharmacies by only using the monthly updates.

NCPA appreciates the opportunity to comment on the Methodology for Calculating the National Average Drug Acquisition Cost (NADAC). We hope that you will take these comments into consideration. Please contact me by email at john.coster@ncpanet.org, or at (703) 600-1184, if you have any questions.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph
Senior Vice President, Government Affairs

cc: Larry Reed, CMS
Joseph Fine, CMS

Center for Medicaid and CHIP Services

Myers and Stauffer LC

Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs

July 26, 2012

Topics

- Welcome and Introductions
- NARP Sample File
- Expected Level of Reporting
- Data Sources and Collection
- Data Management
- Expected Data Methodology
- Quality Assurance
- Q&A

National Average Retail Price

National Average Retail Price (NARP) - is the national average price per unit paid to retail community pharmacy entities from cash customers, third party insurers/customers, and Fee-for-Service Medicaid programs. It includes the combined prices paid for drug ingredient costs, customer pay amounts, and dispensing fees from actual market transactions.

NARP Sample File

Centers for Medicare and Medicaid Services

June 2012 National Average Retail Prices (NARP) Based on April 2012 Claims Data

Drug Name	NDC	Pkg Size	Pricing Unit	Packaging	Rebating Labeler	Active Ingredient(s)	Medicaid Average Retail Price Per Unit (a)	Third Party Average Retail Price Per Unit (b)	Cash Average Retail Price Per Unit (c)	NARP Per Unit (d)	Quantity Most Frequently Dispensed (e)	NARP Per Rx f = (d x e)
ABILIFY 1 MG/ML SOLUTION	59148001315	150.000	ML	BOTTLE		ARIPIPRAZOLE	$4.17485	$4.16851	*	$4.17098	150.000	$625.65
ABILIFY 10 MG TABLET	59148000813	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.84242	$18.80697	*	$18.81519	30.000	$564.46
ABILIFY 15 MG TABLET	59148000913	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.83604	$18.84634	*	$18.84392	30.000	$565.32
ABILIFY 2 MG TABLET	59148000613	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.82202	$18.76884	*	$18.77756	30.000	$563.33
ABILIFY 20 MG TABLET	59148001013	30.000	EA	BOTTLE		ARIPIPRAZOLE	$26.50396	$26.64624	*	$26.61301	30.000	$798.39
ABILIFY 30 MG TABLET	59148001113	30.000	EA	BOTTLE		ARIPIPRAZOLE	$26.41326	$26.68869	*	$26.62810	30.000	$798.84
ABILIFY 5 MG TABLET	59148000713	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.87540	$18.76844	*	$18.79086	30.000	$563.73
ACETAMINOPHEN-COD #3 TABLET	00093015001	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37326	$0.25577	$0.45047	$0.26939	30.000	$8.08
ACETAMINOPHEN-COD #3 TABLET	00093015010	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.35125	$0.26496	$0.54204	$0.28139	30.000	$8.44
ACETAMINOPHEN-COD #3 TABLET	00406048401	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.39530	$0.25607	$0.42553	$0.27076	30.000	$8.12
ACETAMINOPHEN-COD #3 TABLET	00406048410	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.36590	$0.24413	$0.39850	$0.25869	30.000	$7.76
ACETAMINOPHEN-COD #3 TABLET	00603233821	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37799	$0.24798	$0.56257	$0.27429	30.000	$8.23
ACETAMINOPHEN-COD #3 TABLET	00603233832	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37459	$0.24676	$0.52559	$0.28429	30.000	$8.53
ACETAMINOPHEN-COD #4 TABLET	00093035001	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.34278	$0.30021	$0.37727	$0.30312	120.000	$36.37
ACETAMINOPHEN-COD #4 TABLET	00603233921	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.33807	$0.27977	$0.41796	$0.29490	60.000	$17.69
ACETAMINOPHEN-CODEINE ELIXIR	00121050416	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06891	$0.04110	$0.09624	$0.04959	120.000	$5.95
ACETAMINOPHEN-CODEINE ELIXIR	00603102058	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06457	$0.04117	$0.09253	$0.04841	120.000	$5.81
ACETAMINOPHEN-CODEINE ELIXIR	50383007916	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06447	$0.03905	$0.07856	$0.04646	120.000	$5.58

Note: NARP Per RX is equal to the National Average Retail Price Per Unit multiplied by the Quantity Most Frequently Dispensed.

**The number of Cash Observations did not meet the minimum threshold for establishing a Cash Average Retail Price Per Unit. As a result, the National Average Retail Price (NARP) Per Unit was calculated using only Medicaid and Third Party observations.*

NARP Sample File (cont.)

Centers for Medicare and Medicaid Services

June 2012 National Average Retail Prices (NARP) Based on April 2012 Claims Data

Drug Name	NDC	Pkg Size	Pricing Unit	Packaging	Rebating Labeler	Active Ingredient(s)	Medicaid Average Retail Price Per Unit (a)	Third Party Average Retail Price Per Unit (b)	Cash Average Retail Price Per Unit (c)	NARP Per Unit (d)	Quantity Most Frequently Dispensed (e)	NARP Per Rx f = (d x e)
ZOLPIDEM TARTRATE 5 MG TABLET	00603646821	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.26980	$0.25240	$0.56253	$0.26925	30.000	$8.08
ZOLPIDEM TARTRATE 5 MG TABLET	13668000701	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.18528	$0.26174	$0.76545	$0.26482	30.000	$7.94
ZOLPIDEM TARTRATE 5 MG TABLET	16714062101	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.31476	$0.25698	$0.48486	$0.27032	30.000	$8.11
ZOLPIDEM TARTRATE 5 MG TABLET	64679071401	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.18159	$0.27116	$0.43167	$0.27172	30.000	$8.15
ZONISAMIDE 100 MG CAPSULE	64679099001	100.000	EA	BOTTLE		ZONISAMIDE	$0.26856	$0.30231	$0.27278	$0.29594	90.000	$26.63
ZONISAMIDE 100 MG CAPSULE	68462013001	100.000	EA	BOTTLE		ZONISAMIDE	$0.32034	$0.35107	$0.53968	$0.35314	90.000	$31.78
ZONISAMIDE 25 MG CAPSULE	68462012801	100.000	EA	BOTTLE		ZONISAMIDE	$0.22243	$0.23727	$0.50738	$0.24757	60.000	$14.85
ZONISAMIDE 50 MG CAPSULE	64679094601	100.000	EA	BOTTLE		ZONISAMIDE	$0.23881	$0.25089	$0.35021	$0.26499	60.000	$15.90
ZOVIA 1-35E TABLET	52544038328	28.000	EA	BLIST PACK		ETHYNODIOL D-ETHINYL ESTRADIOL	$0.89335	$0.77154	$1.03707	$0.78803	28.000	$22.06
ZOVIRAX 5% CREAM	64455099445	5.000	GM	TUBE		ACYCLOVIR	$40.03531	$39.01568	*	$39.03294	5.000	$195.16
ZOVIRAX 5% OINTMENT	64455099395	30.000	GM	TUBE		ACYCLOVIR	$14.50328	$14.40675	*	$14.41336	30.000	$432.40
ZYPREXA 10 MG TABLET	00002411730	30.000	EA	BOTTLE		OLANZAPINE	$18.66258	$19.14039	*	$18.95981	30.000	$568.79
ZYPREXA 5 MG TABLET	00002411530	30.000	EA	BOTTLE		OLANZAPINE	$12.51166	$12.63307	*	$12.58903	30.000	$377.67

Note: NARP Per RX is equal to the National Average Retail Price Per Unit multiplied by the Quantity Most Frequently Dispensed.

**The number of Cash Observations did not meet the minimum threshold for establishing a Cash Average Retail Price Per Unit. As a result, the National Average Retail Price (NARP) Per Unit was calculated using only Medicaid and Third Party observations.*

Expected Level of Reporting

- The NARP file will be posted to the Medicaid website (http://www.medicaid.gov) on a monthly basis
- The NARP file will be created with Microsoft® Excel and will also be available in an Adobe® PDF format
- Each new file will be a full replacement of the previous file
- Prices are representative of monthly transactions based upon dates of service (dispense date) from two months prior to the published NARP (e.g., April transactions used to calculate NARPs published in June)

Expected Level of Reporting (cont.)

- NARP is expected to be limited to CMS Medicaid covered outpatient drugs (prescription and over-the-counter drugs)
- NARP will be calculated and reported at the 11-digit National Drug Code (NDC) level
- Separate national average prices per unit published for:
  - Fee-for-Service Medicaid programs
  - Third party insurers/customers
  - Cash customers
  - All three payer types as a weighted average - NARP (weighted based on product utilization)

Expected Level of Reporting (cont.)

- Quantity most frequently dispensed
- Estimated NARP per prescription
  - NARP per unit multiplied by quantity most frequently dispensed
- Plan to meet with compendia to discuss sample file layout and update processes

Data Sources and Collection

- Most recent CMS Medicaid covered outpatient drug product file
- Pharmaceutical data suppliers are expected to provide aggregated claims transaction data and utilization data from retail community pharmacy entities
  - Approximately 50 million pharmacy transactions per month
  - Represents actual prices paid to retail community pharmacy entities for drug purchases during the previous month
  - Includes all 50 states and the District of Columbia
  - NDC, dispense date, state, pharmacy entity type, payer type, quantity most frequently dispensed and mean price per unit

Data Sources and Collection (cont.)

- Multiple national drug data files for:
  - NDC validation
  - Labeler, drug name, strength, dosage form, package size, billing unit
  - Medicaid drug rebate DESI code
  - Published pricing data
- NARP file comprised of ~3500 NDC's which are estimated to account for 70% - 75% of a State's Medicaid pharmacy expenditures

Data Management

- Includes only Chain and Independent pharmacy entities
- Medicaid managed care and Medicare Part D included in Third Party payer type
- Data filtering/scrub process
  - Source data in National Council of Prescription Drug Programs (NCPDP) post-adjudication format
  - Data filtering and scrub process reduces the size of the data set by about 3%

Data Management (cont.)

Exclusions

- All pharmacy classifications other than chain or independent retail community pharmacy
- Incomplete, erroneous or aberrant transactions
- Multiple or unknown payer types
- Unit price missing
- Dispensing fee greater than $50
- Discount cards, co-pay cards, manufacturer assistance programs

Data Management (cont.)

Exclusions (cont.)

- NDCs without corresponding utilization data
- NDCs with a CMS DESI value equal to 5 or 6
- NDCs with fewer than 30 claims within Medicaid or Third Party payer types
- Pricing observations which exceed three standard deviations from the average retail price within the same NDC, state and payer type

Expected Data Methodology

- Calculate mean total price per unit (PPU) for each category and each state

State	NDC	Independent	Independent	Independent
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		$1.00 PPU	$.95 PPU	$1.10 PPU
State	NDC	Chain	Chain	Chain
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		$1.00 PPU	$.90 PPU	$1.05 PPU

Data Methodology (cont.)

- Compile estimated utilization for each category and state

State	NDC	Independent	Independent	Independent
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		100 units	500 units	25 units
State	NDC	Chain	Chain	Chain
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		200 units	1,000 units	50 units

Data Methodology (cont.)

- Calculated mean total price per unit (PPU) is then weighted by the estimated utilization for each category in each state

State	NDC	Independent	Independent	Independent
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		$1.00 PPU x 100 units	$.95 PPU x 500 units	$1.10 PPU x 25 units
State	NDC	Chain	Chain	Chain
Ohio	…xx1	Medicaid Customers	Third Party Insurers	Cash Customers
		$1.00 PPU x 200 units	$.90 PPU x 1,000 units	$1.05 PPU x 50 units

Data Methodology (cont.)

State of Ohio, NDC …xx1

- Sum of the product from all categories (PPU multiplied by units) = $1,755
- Divide the above sum by the total number of units for all categories = 1,875 units
- The average retail price for this NDC in Ohio is $1,755 ÷ 1,875 = $.93600 per unit

Data Methodology (cont.)

Basic NARP Calculation Overview

- To calculate a NARP for each NDC, the following steps are taken:
  - A per unit price is calculated for each State/NDC/Pharmacy Entity (chain/independent)/Payer combination
  - The calculated per unit price is weighted based on the estimated utilization for each State/NDC/Pharmacy Entity (chain/independent)/Payer combination
  - The sum of the weighted average per unit prices is divided by the total estimated National utilization to arrive at the National Average Retail Price (NARP)

Quality Assurance

- Monthly reviews
- Sampling of de-identified claims for subset of NDCs to validate aggregated calculations

NARP Sample File

Centers for Medicare and Medicaid Services

June 2012 National Average Retail Prices (NARP) Based on April 2012 Claims Data

Drug Name	NDC	Pkg Size	Pricing Unit	Packaging	Rebating Labeler	Active Ingredient(s)	Medicaid Average Retail Price Per Unit (a)	Third Party Average Retail Price Per Unit (b)	Cash Average Retail Price Per Unit (c)	NARP Per Unit (d)	Quantity Most Frequently Dispensed (e)	NARP Per Rx f = (d x e)
ABILIFY 1 MG/ML SOLUTION	59148001315	150.000	ML	BOTTLE		ARIPIPRAZOLE	$4.17485	$4.16851	*	$4.17098	150.000	$625.65
ABILIFY 10 MG TABLET	59148000813	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.84242	$18.80697	*	$18.81519	30.000	$564.46
ABILIFY 15 MG TABLET	59148000913	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.83604	$18.84634	*	$18.84392	30.000	$565.32
ABILIFY 2 MG TABLET	59148000613	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.82202	$18.76884	*	$18.77756	30.000	$563.33
ABILIFY 20 MG TABLET	59148001013	30.000	EA	BOTTLE		ARIPIPRAZOLE	$26.50396	$26.64624	*	$26.61301	30.000	$798.39
ABILIFY 30 MG TABLET	59148001113	30.000	EA	BOTTLE		ARIPIPRAZOLE	$26.41326	$26.68869	*	$26.62810	30.000	$798.84
ABILIFY 5 MG TABLET	59148000713	30.000	EA	BOTTLE		ARIPIPRAZOLE	$18.87540	$18.76844	*	$18.79086	30.000	$563.73
ACETAMINOPHEN-COD #3 TABLET	00093015001	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37326	$0.25577	$0.45047	$0.26939	30.000	$8.08
ACETAMINOPHEN-COD #3 TABLET	00093015010	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.35125	$0.26496	$0.54204	$0.28139	30.000	$8.44
ACETAMINOPHEN-COD #3 TABLET	00406048401	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.39530	$0.25607	$0.42553	$0.27076	30.000	$8.12
ACETAMINOPHEN-COD #3 TABLET	00406048410	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.36590	$0.24413	$0.39850	$0.25869	30.000	$7.76
ACETAMINOPHEN-COD #3 TABLET	00603233821	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37799	$0.24798	$0.56257	$0.27429	30.000	$8.23
ACETAMINOPHEN-COD #3 TABLET	00603233832	1000.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.37459	$0.24676	$0.52559	$0.28429	30.000	$8.53
ACETAMINOPHEN-COD #4 TABLET	00093035001	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.34278	$0.30021	$0.37727	$0.30312	120.000	$36.37
ACETAMINOPHEN-COD #4 TABLET	00603233921	100.000	EA	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.33807	$0.27977	$0.41796	$0.29490	60.000	$17.69
ACETAMINOPHEN-CODEINE ELIXIR	00121050416	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06891	$0.04110	$0.09624	$0.04959	120.000	$5.95
ACETAMINOPHEN-CODEINE ELIXIR	00603102058	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06457	$0.04117	$0.09253	$0.04841	120.000	$5.81
ACETAMINOPHEN-CODEINE ELIXIR	50383007916	473.000	ML	BOTTLE		ACETAMINOPHEN WITH CODEINE	$0.06447	$0.03905	$0.07856	$0.04646	120.000	$5.58

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NARP Sample File (cont.)

Centers for Medicare and Medicaid Services

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ZOLPIDEM TARTRATE 5 MG TABLET	00603646821	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.26980	$0.25240	$0.56253	$0.26925	30.000	$8.08
ZOLPIDEM TARTRATE 5 MG TABLET	13668000701	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.18528	$0.26174	$0.76545	$0.26482	30.000	$7.94
ZOLPIDEM TARTRATE 5 MG TABLET	16714062101	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.31476	$0.25698	$0.48486	$0.27032	30.000	$8.11
ZOLPIDEM TARTRATE 5 MG TABLET	64679071401	100.000	EA	BOTTLE		ZOLPIDEM TARTRATE	$0.18159	$0.27116	$0.43167	$0.27172	30.000	$8.15
ZONISAMIDE 100 MG CAPSULE	64679099001	100.000	EA	BOTTLE		ZONISAMIDE	$0.26856	$0.30231	$0.27278	$0.29594	90.000	$26.63
ZONISAMIDE 100 MG CAPSULE	68462013001	100.000	EA	BOTTLE		ZONISAMIDE	$0.32034	$0.35107	$0.53968	$0.35314	90.000	$31.78
ZONISAMIDE 25 MG CAPSULE	68462012801	100.000	EA	BOTTLE		ZONISAMIDE	$0.22243	$0.23727	$0.50738	$0.24757	60.000	$14.85
ZONISAMIDE 50 MG CAPSULE	64679094601	100.000	EA	BOTTLE		ZONISAMIDE	$0.23881	$0.25089	$0.35021	$0.26499	60.000	$15.90
ZOVIA 1-35E TABLET	52544038328	28.000	EA	BLIST PACK		ETHYNODIOL D-ETHINYL ESTRADIOL	$0.89335	$0.77154	$1.03707	$0.78803	28.000	$22.06
ZOVIRAX 5% CREAM	64455099445	5.000	GM	TUBE		ACYCLOVIR	$40.03531	$39.01568	*	$39.03294	5.000	$195.16
ZOVIRAX 5% OINTMENT	64455099395	30.000	GM	TUBE		ACYCLOVIR	$14.50328	$14.40675	*	$14.41336	30.000	$432.40
ZYPREXA 10 MG TABLET	00002411730	30.000	EA	BOTTLE		OLANZAPINE	$18.66258	$19.14039	*	$18.95981	30.000	$568.79
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Questions / Comments

- For additional information or to submit questions or comments
  - Email: RPS@cms.hhs.gov
  - Website: http://medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Survey-of-Retail-Prices.html
- For those unable to attend this webinar, a taping of the presentation and related slides will be available on the website above for one week following the webinar

NCPA
NATIONAL COMMUNITY PHARMACISTS ASSOCIATION

WWW.NCPANET.ORG

Submitted via email to RPS@cms.hhs.gov

August 17, 2012

Barbara Edwards
Director, Disabled and Elderly Health Programs Group
Center for Medicaid and CHIP Services
Centers for Medicare and Medicaid Services
7500 Security Blvd
Baltimore, MD 21244

Subject: NCPA Comments on "Part I: Draft Methodology for Estimating the National Average Drug Retail Prices (NARP) for Medicaid Covered Outpatient Drugs"

Dear Barbara:

On behalf of the National Community Pharmacists Association (NCPA), I am writing regarding the recently released CMS document, "Draft Methodology for Estimating the National Average Drug Retail Prices (NARP) for Medicaid Covered Outpatient Drugs." NCPA appreciates the opportunity to review this document and to provide our comments and concerns before these data are released and states or other payers possibly use the data to set reimbursements.

NCPA represents the owners and operators of approximately 23,000 privately-held small business independent community pharmacies across the United States. Our members provide about 40 percent of all outpatient prescriptions in the United States. Moreover, more than 90% of NCPA members' business is derived from prescription revenues, and Medicaid represents an average 15% of all prescriptions filled. This percentage is higher for pharmacies in urban and rural areas. NCPA members are on the front lines of Medicaid beneficiary care, and are more significantly impacted by new methodologies than other pharmacy entities.

NCPA continues to be very concerned about CMS' haphazard approach to implementing Medicaid pharmacy reimbursement changes. This includes CMS insistence on publishing eleven, problematic draft FUL lists for Medicaid generic drugs that will devastate small business pharmacies if implemented, the development of a NADAC program for which we believe that CMS lacks authority to implement, and now a NARP program that violates the intent of the Social Security Act.

Under Section 1927(f)(1)(A)(i) of the Social Security Act, the Secretary may contract for services for… the determination on a monthly basis of retail survey prices for covered outpatient drugs that represents a nationwide average of consumer purchase prices for such drugs…" The statute is clear that the survey should consist of consumer purchase prices. Yet, CMS is including commercial third party payments, including Medicaid payments, in the calculation of the NARP, which are not consumer purchase prices.

100 Daingerfield Road
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(703) 683-8200 PHONE
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In addition, these are NCPA's comments on the proposed NARP methodology:

- There are too many different unidentified data files and too much estimation being used in this proposed methodology for CMS to even contend that these NARP values will be remotely credible. Releasing these data into the marketplace could have a widespread negative economic impact on small businesses – beyond the Medicaid program – if the NARP understates the amount that pharmacies receive for prescriptions, and the amounts are used as a reimbursement benchmark.

- The NARP methodology must include a mechanism to back out the millions of dollars in Medicaid copays that go unpaid every year to pharmacies. Unlike private plans, pharmacies cannot collect copays from Medicaid patients if they theoretically cannot pay or refuse to pay the required copay. States cannot and do not compensate pharmacies for such lost copays. Therefore, lack of copay collection represents a reduction in Medicaid revenues to pharmacies, which is what NARP is supposed to measure. Without this adjustment, the average revenues to pharmacies will be overstated and therefore the NARP is not an accurate methodology.

- The definition of community retail pharmacy should be adopted as part of the methodology. That is, it should be made clear that only true independent or chain pharmacies should be included. If Section 1927 is changed by a future Congress, it may create confusion as to the definition of a retail community pharmacy.

- The methodology is cryptic as to the "data suppliers" being utilized by Myers and Stauffer to determine the mean price per unit. In the interest of "full transparency" which CMS repeatedly claims it places a priority on maintaining, it must disclose the sources of the data used by the contractor to determine the NARP so that the underlying data could be validated. The use by CMS or its contractors of anonymous "data suppliers" is arbitrary and capricious.

- CMS must clarify why utilization used to calculate price for each NDC/state/payer type/pharmacy entity comes from one data source, yet the monthly utilization file used to calculate NARP at the NDC/payer type level comes from another data source.

- CMS must clarify how "data suppliers" will work together to create one master file that will then be turned over to Myers and Stauffer. Will one "data supplier" provide data on cash transactions while another "data supplier" provides data on "other" types of transactions? Will "data suppliers" be stratified by geographic region? If "data suppliers" use different methodologies to capture and measure transaction prices, how will they develop an accurate and standard measure?

- Some retail community pharmacies serve LTC facilities and 340b entities. Claims for 340B drugs and all LTC claims must also be excluded from the calculation. There will simply be no credibility to the data if such claims are included because payments to these other entities for the same drugs might be lower than the payments made to community pharmacies. The anonymous "data suppliers" must find a way to exclude these LTC claims from the data used to collect the NARP.

- The methodology states that specialty pharmacies will be excluded from the NARP at this time. Specialty pharmacies should never be included in the calculation. CMS must clarify what definition they are utilizing for specialty pharmacies.

- CMS must clarify that the Medicaid price included in the calculation is the actual price paid to the pharmacy, if the pharmacy is paid at the lower usual and customary price. The higher amount that would be paid to the pharmacy based on the state's reimbursement formula should not be included.

- CMS must clarify how they will ensure there is a representative sample across pharmacy channels *within each state/payer type calculation*. CMS states that 30 observations are necessary to calculate an average retail price, but it is unclear if 30 observations are required at the NDC level or at the pharmacy channel/state/payer type level.

- CMS must clarify if the aggregated data that CMS plans to utilize to project utilization is weighted by both chains and independents so that there is accurate representation of the amounts received by independents.

In summary, we believe that CMS is violating the statue by including prices other than consumer purchase prices in this methodology. Moreover, the sheer number of different unnamed unidentified files being used, and the various weighting and estimation processes being used, allows for the introduction of so much error in the outcomes that we question the credibility of the results. The potential economic damage to small businesses through the public release of these data is real. We hope that you will take these comments into consideration. Please contact me by email at john.coster@ncpanet.org, or at (703) 600-1184, if you have any questions.

Sincerely,

John M. Coster

John M. Coster, Ph.D., R.Ph
Senior Vice President, Government Affairs

NACDS NATIONAL ASSOCIATION OF CHAIN DRUG STORES

VIA Electronic Submission

RPS@cms.hhs.gov

August 17, 2012

Mr. Joseph Fine
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Subject: Draft Methodology for Estimating National Average Retail Prices (NARP) for Medicaid Covered Outpatient Drugs

Dear Mr. Fine:

On behalf of the National Association of Chain Drug Stores (NACDS) and its membership, thank you for the opportunity to provide comments on the draft methodology for estimating National Average Retail Prices (NARP) (hereafter "Draft Methodology").

413 North Lee Street
Alexandria, Virginia
22314

NACDS represents traditional drug stores, supermarkets, and mass merchants with pharmacies – from regional chains with four stores to national companies. Chain pharmacies are the primary providers of prescription medications in both the Medicaid and Medicare Part D programs. They fill over 2.6 billion prescriptions annually, which is more than 72 percent of annual prescriptions in the United States.

Section 6001(e) of the Deficit Reduction Act of 2005 (DRA) states the Centers for Medicare & Medicaid Services (CMS) may have a contractor conduct a "nationwide survey of consumer purchase prices" for drugs. In addition, Section 2503 of the Affordable Care Act (ACA) clarifies what transactions should be included in NARP, and authorizes the disclosure of NARP for certain multiple source drugs to the public.

We are concerned that CMS's implementation of NARP, as described in the Draft Methodology and on the webinar hosted by the Agency on July 26, 2012, exceeds the requirements of both the Deficit Reduction Act and the Affordable Care Act. In order to implement NARP in a manner consistent with congressional intent, we urge CMS to utilize formal rulemaking with an opportunity for public comments before calculating and posting NARP.

Calculation of National Average Retail Prices

The authority provided by the DRA and the ACA is limited to the monthly calculation of a single retail survey price, or NARP. This NARP is specific to retail community pharmacies and is to "represent a nationwide average of consumer purchase prices" for covered outpatient drugs.

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Despite this limited authority, the Draft Methodology states CMS intends to calculate NARPs not only for cash paying consumers, but also NARPs for transactions involving purchases by insurance companies and Medicaid programs. Such entities fall outside of the definition of "consumer" and, therefore, fall outside the scope of the DRA and ACA. Consequently, we respectfully request that CMS discontinue efforts to calculate an unauthorized collective cash, third party, and Medicaid NARP and instead follow the requirements of the DRA and ACA to calculate a single NARP based on "consumer" purchase prices.

The Affordable Care Act also makes clear that NARP is to be limited to purchase prices at retail community pharmacies, which are defined as "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices." 42 U.S.C. § 1396r-8(k)(10). The definition of retail community pharmacy in the Affordable Care Act is unequivocal. Nevertheless, the Draft Methodology states, "Specialty pharmacies will be excluded from the NARP *at this time*" (emphasis added). Specialty pharmacies should not be part of NARP, as they are not retail community pharmacies. If data from specialty pharmacy or other entities that are not retail community pharmacies are included in NARP calculations, NARP will not be reflective of consumer purchase prices at retail community pharmacies.

Disclosure of National Average Retail Prices

The Affordable Care Act limits public disclosure to average retail survey price for multiple source drugs subject to Federal Upper Limits (FULs). Subsequently, public posting of NARPs should be limited to weighted average NARPs for multiple source drugs subject to FULs, and those NARPs should be based on consumer prices paid at retail community pharmacies.

In the Draft Methodology, CMS incorrectly states, "The purpose of the NARP is to publish a monthly pricing database for Medicaid covered outpatient drugs that is based on actual monthly market transactions" (Draft Methodology for Estimating National Average Retail Prices of Prescription Drugs, page 4). NACDS has been unable to identify anything in the statutory language or legislative history of the DRA or the ACA that suggests Congress intended CMS to create a "pricing database." In fact, the provisions in the Affordable Care Act relating to retail survey price are meant to place limits on the actions of CMS in this area. The ACA makes clear that data collection is restricted to retail community pharmacies and that public disclosure of data is limited to average retail survey prices (NARPs) for multiple source drugs subject to FULs.

NACDS is also concerned with the high level of confusion disclosure of NARPs is likely to create. Currently, CMS is posting draft FULs based on 175% of weighted average manufacturer price, and well as weighted AMPs. These values are published at the unit level (i.e., per pill). In contrast, the Draft Methodology states NARPs will be disclosed at the average price per prescription (i.e., 30-day supply)

and will also include the pharmacy dispensing fee and patient co-payments and other cost sharing. Despite the fact that NARP is described as a "comparison tool," its makeup, which is unlike any other pharmacy benchmark, does not provide for an accurate comparison. NACDS urges CMS to post a prominently displayed explanation of the NARP data on its website, explaining the difference between AMPs, FULs and NARPs.

Draft NARP Methodology

NACDS appreciates the additional detail provided by CMS with regard to the draft NARP methodology. However, we do have some concerns with the lack of sufficient detail and believe clarification from CMS is needed. For example, the draft methodology states that claim data from "data suppliers" will be collected to calculate the NARP. Because no additional information on "data suppliers" is available, it is unclear if CMS will have access to reliable data to determine NARP. If multiple data vendors are utilized as suppliers of claims data, it is unclear how CMS will ensure that duplicate claims are not included across "data suppliers" or if multiple data vendors are using the same internal methodology for their calculations. NACDS urges CMS to identify the entities that are supplying claims data for NARP calculations in order to determine if the data is representative of pharmacy.

The Draft Methodology fails to take into account the impact of uncollected co-payments on pharmacy reimbursement in the Medicaid program. Despite the fact that cost sharing is meant to be the responsibility of the beneficiary, too often pharmacies bear the cost of uncollected co-payments, and incur a loss when Medicaid patients refuse to pay their cost sharing. Medicaid providers have historically been able to collect only 50 percent of all co-payments assessed.[1]

We have also been unable to find information in the Draft Methodology regarding how recoupment will be addressed. Payments to pharmacies that are recouped at a later date should not be included in NARP calculations.

In addition, while CMS acknowledges prescription drug prices may not be captured from all pharmacies, it is unclear how CMS will determine whether or not it has obtained a representative sample.

Conclusion

Thank you for the opportunity to provide comments on the Draft Methodology.

Sincerely,

Julie Helm Khani
Vice President, Public Policy

[1] *Medicaid Cost Sharing,* Department of Health and Human Services, Office of the Inspector General, July 1993, page 13.

HDMA
Healthcare Distribution Management Association

July 24, 2012

BY ELECTRONIC FILING
http://www.regulations.gov

Docket Management System
U.S. Department of Transportation
Dockets Operations, M-30
Ground Floor, Room W12-140
1200 New Jersey Avenue, SE
Washington, DC 20590-001

Re: ***Hazardous Materials: Harmonization With the United Nations Recommendations on the Transport of Dangerous Goods: Model Regulations, International Maritime Dangerous Goods Code, and the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air, 49 CFR Parts 171, 172, 173, 175, 176, and 178*** **[Docket number: PHMSA-2009-0126 (HM-215K); RIN 2137-AE83]**

Dear Michael Stevens and/or Shane Kelley:

On behalf of the Healthcare Distribution Management Association (HDMA), I am pleased to submit public comments in response to the May 25, 2012 proposal (77 Fed. Reg. 31274) from the US Department of Transportation, *Pipeline and Hazardous Materials Safety Administration (PHMSA)*. The proposal responds to several administrative appeals submitted to PHMSA on the January 19, 2011 final rule revising the Hazardous Materials Regulations (HMR) (76 Fed. Reg. 3308), including the appeal filed by HDMA on June 17, 2011.

We are pleased that PHMSA has recognized the concerns raised by HDMA and as a result, is proposing further amendments to the HMR. While extending the deadline to December 31, 2015 to use ORM-D (Other Regulated Material – Domestic) embossed plastic totes is a welcomed change, the additional two years being proposed is, quite frankly, inadequate and the adopted regulation will still impose millions of dollars of costs on the healthcare distribution industry with no associated public health benefit.

HDMA has found that PHMSA has significantly underestimated the compliance costs that healthcare distributors will incur and has not effectively considered the potential for the regulation to trigger marketplace disruptions. HDMA respectfully but strongly believes that PHMSA's own compliance cost estimate, which provides that over the course of 10 years $22 million will be spent on labeling, does not justify eliminating a dual marking system where the ORM-D logo is considered synonymous with the new Limited Quantity (LQ) UN Diamond logo.

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As the attached comments explain, the costs of labeling could be nearly $250 million after 10 years and nearly $350 million after 20 years. As such, HDMA continues to believe that to comply with the January 2011 regulation, most healthcare distributors will replace their ORM-D embossed totes with UN Limited Quantity embossed totes. Additionally, HDMA members are busy incorporating numerous other enhancements into the distribution system, such as programs designed to discourage the introduction of counterfeit drugs. Any activities, such as labeling, that take away from these more important upgrades should be avoided.

For these and the other reasons described, we respectfully request that PHMSA reconsider HDMA's previous recommendation of allowing totes that are already in commerce and embossed with ''Consumer Commodity, ORM–D" to remain in use for US domestic highway, rail and vessel transportation. Alternatively, PHMSA should extend the authorization period for use of ORM-D designation until 2020, thereby enabling additional time that will reduce the impact of the regulatory change.

Lastly, if PHMSA is unwilling or perhaps uncertain about granting HDMA's requests, we encourage PHMSA to immediately issue an "interim" final regulation that would grant the additional two years so that healthcare distributors are not forced to prepare to comply with the January 2011 regulation; in the intervening period, PHMSA can further evaluate HDMA's requests.

HDMA appreciates the opportunity to provide our views. If there are any questions, please do not hesitate to contact me at 703-885-0240 or at aducca@hdmanet.org.

Respectfully submitted,

Anita T. Ducca

Anita T. Ducca
Vice President, Regulatory Affairs

Attachments

HDMA's 2012 Regulatory Affairs Comments, Statements and Meetings

	Name	File Date
1	Comments to FDA on Bar Code Rule	1/6/2012
2	Comments to FDA on MedGuides	2/8/2012
3	Comments to FDA on Label Changes	2/17/2012
4	Statement to FDA on Conditions of Safe Use	3/22/2012
5	Comments to FDA on Conditions of Safe Use	5/4/2012
6	Presentation at USP's Public Workshop on Supply Chain Integrity	5/23/2012
7	Comments to FDA on MedGuides	5/25/2012
8	Joint Comments to DOT on ORM-D Extension	7/23/2012
9	Comments to DOT on ORM-D Extension	7/24/2012

HDMA's 2012 CMS Comments, Statements and Meetings

	Name	File Date
1	Comments to CMS on the Sunshine Act	2/17/2012
2	Joint Comments to CMS on AMP (Abuse Deterrent Formulations)	3/28/2012
3	Joint Comments to CMS on AMP (Presumed Exclusion)	4/2/2012
4	Comments to CMS on AMP	4/2/2012
5	Meeting with CMS on NADAC	4/10/2012
6	Comments to CMS on NADAC	6/21/2012

Examples of the USP Draft <1083> "Good Distribution Practices – Supply Chain Integrity" ("draft 1083" or "the draft") Specific Issues
See: http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/revisions/c1083.pdf

- States may assume that because draft 1083 contains extensive discussions of RFID that the supply chain is prepared to move towards RFID technology and regulate accordingly.

- Under "Establishment of Drug Pedigrees," draft 1083 states:

  If a drug container's contents are subdivided during repackaging or if the manufacturer's smallest unit-of-sale package (e.g., prefilled syringes) is repackaged and sold individually, then a new and unique SNI ***must be applied*** *to each unit of the subdivided packaging and to each of the separated drug-filled containers.* [Emphasis added]

  Thus, state adoption of draft 1083 may limit a manufacturer's flexibility to decide when and under what conditions to repackage the product and apply a different SNI.

- Draft 1083 contains terms whose meanings are still evolving in technical, legislative and regulatory circles. This could lead to confusing, inappropriate or inconsistent requirements should states incorporate the draft into their laws. For example,
  - "Pedigree" or "Pedigree Systems" appear to be used interchangeably with what is more often referred to as "traceability". To quote:

    "*Most envisioned pedigree systems entail giving each prescription drug package a unique identifying code called a standardized numerical identifier (SNI) at the point of manufacture.*"

    However, most state laws envision "pedigree systems" as paper-based and/or do not involve the SNI, whereas the SNI is more frequently associated with "traceability".

  - Under the section titled "Repackaging Guidance, Information Retention, and Security" draft 1083 states: "*All the information collected in the drug pedigree for each unit of sale for each batch* ***should be retained for the same period of time as all other batch records.***" [Emphasis added]

    (1) Under federal regulations, and the applicable duration for keeping pedigrees is set in years. (21 CFR 203.50(b) requires 3 years, and includes repackagers). States may require longer durations. There is obviously a potential for confusion between a duration based on batch record retention and laws based on years. The complying entity may also need to set up dual record retention tracking methodologies to document compliance with the federal or state duration, plus the separate USP-defined duration.

    (2) Although it is implied that the record retention applies only to repackaging, the draft doesn't directly or clearly state so. If state regulators are uncertain, they may sweep the entire supply chain under a "batch record" duration requirement – and we will have more variability among the states regarding the record retention period.

(3) Since serialization technologies and laws are still under development, it is highly premature for draft 1083 to include any discussion of requirements related to serialization and repackaged products.

- The section titled "Application of Machine-Readable Data Carriers to Drug Products" states: "…2D bar codes and/or RFID tags ***are required***…." [Emphasis added] implies that there is an existing requirement to place 2D bar codes or RFID on packages. To date, only CA requires a machine-readable system, but even their laws don't specify a technology.

2012 DISTRIBUTION CENTER CHALLENGE

THE CHALLENGE

To participate in the newest HDMA advocacy initiative by scheduling a distribution center tour with your local congressman or senator during fall congressional recess periods.

WHY THE FALL?

Legislators return to their district or state during congressional recess periods to meet with constituents, hold town-hall meetings and interact with citizens and businesses within the district or state they represent. This presents a window of opportunity for scheduling an in-district site visit to your company's pharmaceutical distribution center.

WHY A DISTRIBUTION CENTER TOUR?

Effective advocacy begins with face-to-face communications and hands-on demonstrations with legislators so they can better understand your operations. Facility tours provide you and your staff an opportunity to develop relationships with your legislators, put a face and name behind your business, and give a first-hand description of the facility's capabilities and the value of healthcare distributors in the industry. Inviting a legislator to visit your distribution center provides mutual benefit and is a chance to generate a real learning experience for your legislative representatives.

HOW DO I GET STARTED?

First, review the enclosed materials and determine your timeline for inviting, scheduling and engaging your congressional representative or senator.

Second, determine which legislator you would like to invite. Do not be afraid to schedule multiple tours during the August recess for more than one legislator, but note that tours should be scheduled individually with each legislator.

Third, follow the steps in the "Distribution Center Tours: Planning from A-Z" guide to prepare for the tour.

Fourth, gather information to help demonstrate to the legislator the impact of your company and your business on the district. Use the "Distribution Center Tour: Points of Interest" as a guide.

For more information, contact Jewelyn Wellborn at jwellborn@hdmanet.org or (703) 885-0272.

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HDMAPAC
POLITICAL ACTION COMMITTEE

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HDMA Issues / Initiatives
Dashboard - Fourth Quarter 2012

Q4 2012
Updated: 9/12/12 - PROPOSED

Initiative	Status							
	FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
A Priorities								
340B Issues	2			2				2
Biotechnology / Specialty				1	1	1	1	1
Controlled Substance Issues ~~Rules / Enforcement~~	1	1	1	2	1		1 2	
Distributor Licensing / Accreditation	1	1			1			
Drug Shortages / Product Availability	1	2	1 2	1	1		1	1
Generic Drugs: Issues	2	2		2	2	2		
Healthcare Standards (Serialization, etc.)			1	1	2	2	1	
Importation / Import Safety	1				1			
Supply Chain Security	2	1	2	1	1	1	1	
Marketing and Gift Restrictions		2	1					
Medicaid: AMP / RSP / AAC / WAC	1	2	1		1		1	1
Medicare: Part B ASP (Prompt pay/CAP)	1		2		2			1
Pedigree Requirements	1	1	2	1	1	1	1	1
Pseudoephedrine / Dextromethorphan	2	1	2					
Role of Distributor Study					1	1		
Tax Issues (Gross Receipts and LIFO)	1	1			1			
Wholesaler Price Reporting		1	2					
B Priorities								
Cold Chain Best Practices			2	1		2	1	2
Conditions for Safe Use			2					
Contract Administration				1			1	
Counterfeiting Alert Network (CAN)			2		1			
DOT Issues			2 1					
EDI Guideline Updates				1			1	
Emergency Preparedness / Pandemic Influenza	2	2	2	1	2		2 1	
Health, Beauty & Wellness				1	2		2	
Internet Pharmacy	2		2					
NDC Rule (Repackaging/Relabeling)			2	2	2			
Non-Approved Drugs			1 2					
PBM Transparency	2	2						
Returned Goods		1	2	1	2	1	1	
Risk Eval Mitigation Strategies (REMS)	2		2	2	2	1	2	
Rx Waste / Disposal	1	1	1	2		1	1	
Seasonal Influenza	2	2	2	2	2			

HDMA Issues / Initiatives
Dashboard - Fourth Quarter 2012

Q4 2012
Updated: 9/12/12 - PROPOSED

C Priorities

Initiative	Status							
	FGA	SGA	Reg	IR	PA	Cntr	Edu	SBDC
Bar Code Rule			2					
Future of Healthcare Study						2		
Health IT	2		2		2	2		
Labor / Card Check	2		2					
Patient Privacy/HIPAA	2	2	2		2			

Long Term Consideration

	Date Added	Notes
Consolidation	4/6/2007	
Future of Pharmacy (Pharmacy 2020)	4/6/2007	
Health IT	4/6/2007	
International Distribution	4/6/2007	
Risk Management	4/6/2007	
Sustainability/Corporate Social Responsibility	8/10/2007	
Vertical Integration	4/6/2007	

Removed

	Date Removed	Reason
856 Ship Notice w/ Healthcare Product Data	2/3/2011	Contained in EDI and Healthcare Standards
1099 Reporting	8/1/2011	Issue resolved
BioShield Reauthorization	2/7/2007	Issue resolved
Data Management Study	2/3/2011	Contained in Healthcare Stds and Pedigree
DEA CSOS: EDI Guidelines	4/6/2007	All related issues now under DEA CSOS
DEA Fees	4/6/2007	Combined with DEA Rules
DME Accreditation / Surety Bond	9/15/2010	
DOD - Tricare	2/7/2007	Issue resolved
Generic Drugs: EPC / RFID Cost-Benefit	4/6/2007	Contained under Rx SafeTrack
Generic Drugs: Settlements/Reimbursement	4/6/2007	Combined under Generic Drug Issues
Healthcare Reform (non-HDMA priorities)	1/28/2011	Bill signed into law in 2010
Medicare Part D / Price Negotiation / Other	9/15/2010	
PDMA Regulations and Requirements	2/7/2007	Combined with Pedigree Requirements
PDUFA (Rx Manufacturer User Fees)	7/2/2007	
Repackaging	2/7/2007	Combined with NDC Rule
Rx SafeTrack	1/28/2011	Formal effort no longer operating
State Bulk Purchasing	8/1/2008	No state activity
Thymerisol	7/2/2007	
Track & Trace Standards	2/7/2007	Combined into EPC Standards

STATUS: 1 = Active Project or Issue; 2 = Monitoring / Emerging
PRIORITY: A = High for organization and/OR Industry; B = Medium; C = Low

PROPOSED DASHBOARD CHANGES

"A" Priorities

Federal Government Affairs

- NO CHANGES

State

- MODIFY (A2) *Generic Drugs: Issues*
  - With the emergence of the generic competitive bidding issue in the states in 2012, this issue continues to receive more attention.

Regulatory

- MODIFY (from A1 to A2) *Drug Shortages/Product Availability*
  - For distributors, the focus has shifted away from FDA to the Hill.

"B" Priorities

Federal Government Affairs

- NO CHANGES

State

- NO CHANGES

Regulatory

- MODIFY (B2 to B1) *DOT Issues*
  - Stepped up activities – *i.e.*, proposed rule on totes and ANPRM on reverse logistics.
- MODIFY (B1 to B2) *Non-Approved Drugs*
  - Have achieved greater clarity on expectations for distributors.

"C" Priorities

- NO CHANGES